

**VANCOUVER HOSPITAL & HEALTH SCIENCES CENTRE
CSU PHARMACEUTICAL SCIENCES
SPECIAL ACCESS (SAP) DRUG DATA SHEET**

DRUG NAME

Arsenic

ALTERNATE NAME

Arsenic Trioxide, ATO, As₂O₃,
Trisenox ®

MANUFACTURER

Cell Therapeutics, Inc.

STRENGTH

1mg/mL (10mL ampoule)

DOSAGE FORM

Injection

INDICATIONS

- Treatment of refractory or resistant chronic and acute myeloid leukemias, acute promyelocytic leukemia, multiple myeloma, and myelodysplastic syndromes.

DOSAGE AND ADMINISTRATION

- Induction Therapy for adults and children ≥ 5 years: 0.15 mg/kg IV once daily over 1-2 hours until bone marrow remission. Total induction should not exceed 60 doses.
- Consolidation Therapy for adults and children ≥ 5 years: 0.15 mg/kg IV once daily over 1-2 hours for 25 doses over a period of up to 5 weeks (i.e., may be given weekdays only during consolidation) beginning 3-6 weeks after completion of remission therapy. No more than 4 days should elapse between treatment days.
- *CALGB C9710 Study Protocol*: 0.15 mg/kg/day IV for 5 days/week x 5 weeks. Rest 2 weeks. Then repeat cycle. (Dose may be reduced to 0.075 mg/kg/day if toxicities develop.)
- Dilute in 100-500mL D5W or NS prior to administration.

KNOWN SIDE EFFECTS*

- Most common (>25%): nausea, vomiting, diarrhea, abdominal pain, sore throat, fatigue, fever, edema, rigors, cough, dyspnea, headache, insomnia, neutropenia, thrombocytopenia, hyperglycemia, hypokalemia, hypomagnesemia, dermatitis, pruritus, tachycardia.
- Other: APL Differentiation Syndrome (i.e., fever, dyspnea, weight gain, pulmonary infiltrates, pleural or pericardial effusions with or without leukocytosis), prolonged QT interval, atrial fibrillation/flutter, liver function test abnormalities, renal dysfunction, arthralgia, myalgia, hemorrhage, infection, pain, leukocytosis, peripheral neuropathy, sensory loss, ataxia, agitation, confusion, skin dryness.

SPECIAL PRECAUTIONS

- Prepare under biohazard hood.
- Unused portions can be transferred to an empty vial and kept for 48 hours at room temperature.
- May be administered via central or peripheral Line.
- Do not mix with any other medication.
- Use with caution in patients with renal failure, in patients receiving drugs that may prolong the QT interval (e.g. antiarrhythmics, thioridazine) and drugs that may cause electrolyte disturbances (e.g., potassium sparing diuretics, amphotericin B).
- Treatment should be interrupted in patients with significant hepatotoxicity, nephrotoxicity, neurological impairment (somnolence, seizures, impaired mentation) peripheral neuropathy, or any non-hematologic grade 4 toxic event.
- Extravasation: See protocol for Non-vesicant antineoplastic agents.

***REPORT ANY ADVERSE DRUG REACTIONS TO CSU PHARMACEUTICAL SCIENCES**

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